EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

THIS ORDER RELATES TO:

HARDEN MANUFACTURING CORPORATION; LOUISIANA HEALTH SERVICE INDEMNITY COMPANY, dba BLUECROSS/BLUESHIELD OF LOUISIANA; INTERNATIONAL UNION OF OPERATING ENGINEERS, LOCAL NO.68 WELFARE FUND; ASEA/AFSCME LOCAL 52 HEALTH BENEFITS TRUST; GERALD SMITH; and LORRAINE KOPA, on behalf of themselves and all others similarly situated, v. PFIZER INC. and WARNER-LAMBERT COMPANY.

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THE GUARDIAN LIFE INSURANCE CO. OF AMERICA v. PFIZER, INC. and
AETNA, INC. v. PFIZER, INC.

MDL Docket No. 1629
Master File No. 04-10981
Judge Patti B. Saris
Mag. Judge Leo T. Sorokin

REPORT AND RECOMMENDATION ON DEFENDANTS' MOTIONS TO DISMISS THE AMENDED CLASS COMPLAINT AND THE FIRST COORDINATED AMENDED COMPLAINT

January 31, 2006

SOROKIN, M.J.

I. INTRODUCTION

In this putative class action, Plaintiffs allege that they were injured by Defendants' fraudulent scheme to market and sell the drug Neurontin (gabapentin) for a variety of conditions

for which it was neither approved by the FDA nor shown to be medically effective. This matter is before me on Defendants' Motions to Dismiss the Amended Class Complaint[1] and the First Coordinated Amended Complaint.[2] Defendants to both Complaints are Pfizer, Inc. and Warner-Lambert Co. Pfizer began selling Neurontin upon its acquisition of Warner-Lambert in 2000. Prior to 2000, Neurontin was marketed and sold by Parke-Davis, a division of Warner-Lambert.[3]

The Amended Class Complaint asserts five counts: violation of the federal Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1962(c) (Count I); violation of 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c) (Count II); violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq*. (Count III); Common Law Fraud (Count IV); and Unjust Enrichment (Count V).

The First Coordinated Amended Complaint asserts thirteen counts. The first counts allege RICO violations, asserted against various enterprises (Counts I through IX). Coordinated

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[1] The group of Class Plaintiffs consists of Harden Manufacturing Corporation; Louisiana Health Service Indemnity Group d/b/a/ Blue Cross/ Blue Shield of Louisiana; Union of Operating Engineers, Local No. 68 Welfare Fund; ASEA/AFSCME Local 52 Health Benefits Trust, and two named individuals, Gerald Smith and Lorraine Kopa. Plaintiffs assert claims on behalf of two subclasses: (1) "[a]ll private, non-governmental entities...that are at risk...to pay or reimburse all or part of the cost of Neurontin prescribed...for indications not approved by the FDA,", and (2) "[a]ll individuals . . . who . . . paid for . . . Neurontin, for indications not approved by the FDA."

[2] The Coordinated Plaintiffs are Guardian Life Insurance Co. of America; Kaiser Foundation Health Plan, Inc.; Kaiser Foundation Hospitals; and Aetna, Inc.

[3] The instant litigation comes in the wake of a lengthy *qui tam* action filed by one of Pfizer's former medical liaisons, Dr. David Franklin. See United States ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39 (D.Mass.2001) (Saris, J.) (in which Relator alleged that Pfizer engaged in a fraudulent and illegal marketing campaign to promote Neurontin for off-label uses). In 2000, Pfizer pled guilty to illegal off-label marketing and paid criminal and civil settlements of $430 million.

Plaintiffs also assert claims for violation of California's Unfair Competition Law (Count X); violations of the Consumer Protection Statutes of the remaining 49 states, the District of Columbia, and Puerto Rico (Count XI); insurance fraud in violation of Pennsylvania Law (Count XII); and Restitution/Disgorgement for Unjust Enrichment (Count XIII).

Defendants have moved to dismiss both Complaints. For the reasons set forth below, I recommend to the District Judge to whom this case is assigned that the Motions to Dismiss be ALLOWED in part and DENIED in part. I recommend that the Court DISMISS the RICO claims in both Complaints and DISMISS in part the remaining state law claims. In addition, I recommend that all plaintiffs be allowed sixty days from the date of the Court's decision on this Report and Recommendation to file amended complaints.

II. FACTUAL BACKGROUND[4]

Pfizer is a major American pharmaceutical company based in New Jersey. It manufactures and distributes Neurontin, a drug approved in 1993 by the Food and Drug Administration (FDA) for use as an "adjunctive therapy"[5] for the treatment of partial seizures in adults with epilepsy.[6] The FDA-approved labeling of Neurontin indicates that the drug is

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[4] The First Coordinated Amended Complaint tracks in most part the Amended Class Complaint. Factual allegations have been drawn from both Complaints, and I cite to the Amended Class Complaint when referring to facts alleged in both Complaints. In those instances where the factual allegations differ, the First Coordinated Amended Complaint is cited separately.

[5] "Adjunctive therapy" means that the drug can not be prescribed by itself, as a "monotherapy" for the treatment of epilepsy. Rather, it is required to be used in combination with another epilepsy drug.

[6] In May of 2002, the FDA also approved Neurontin for management of postherpetic neuralgia, pain resulting from nerve damage caused by shingles.

effective at doses ranging from 900 milligrams to 1800 milligrams per day. Amended Class Complaint (hereinafter "ACC"), ¶ 17.

In the late 1980's and early 1990's, Parke-Davis filed several patent applications for Neurontin as a treatment for depression, neurodegenerative disease, mania, bipolar disorder and anxiety. However, it did not seek FDA approval for these indications. ACC, ¶ 20. This is significant because, except under limited circumstances, a drug manufacturer is prohibited from promoting a drug for a use for which the drug has not received approval from the FDA. Such use is known as an "off-label use". [7] See Franklin, 147 F.Supp.2d at 44. In recognition of both the notion that medical practitioners can best determine what therapy would most benefit their patients, and the long-held view that the FDA does not regulate the practice of medicine, a physician remains free to prescribe a drug for whatever uses she deems medically appropriate, including off-label uses. See Buckman Co. v. Plaintiffs' Legal Comm., 531 US 341, 350 (2001).

In May of 1994, Parke-Davis estimated that, based on Neurontin's narrow use as an adjunctive therapy for epilepsy, its sales potential was a modest $500 million over the lifetime of the drug. In an effort to increase sales of Neurontin, Parke-Davis chose to implement a

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[7] There are a few exceptions to the FDA's general prohibition on marketing a drug for off-label uses. According to FDA Guidelines, a drug manufacturer may provide an unrestricted grant to an "accredited independent sponsor" of continuing medical education programs, provided that it does not influence the content of the program by selecting the content or approving the speakers. A manufacturer is also permitted to communicate off-label information in response to a bona fide, unsolicited request from a physician, provided such information was specifically responsive to the physician's request. Finally, a drug company is permitted to provide copies of published articles about off label usage, provided such materials were responsive to the request and the presentation was fair and balanced. ACC, ¶¶ 35-39. See also 21 U.S.C. § 360aaa *et seq.*

"publication strategy," the aim of which was to disseminate information about Neurontin for off-label uses. The publication strategy was deemed a sound alternative to performing clinical trials sufficient to obtain FDA approval, which would be at least three times more costly. ACC, ¶ 27. When Parke-Davis decided to pursue this marketing strategy rather than seek FDA approval for other potential uses for Neurontin, it knew that it lacked the type or amount of research data necessary for FDA approval. ACC, ¶ 20. It also knew that Neurontin worked by a different mechanism than did other anti-epileptic drugs and, therefore, research regarding those drugs did not apply to Neurontin. ACC, ¶ 22.

At issue in this matter is Pfizer's alleged promotion of Neurontin for off-label uses in an effort to reap increased profit margins. The Complaints allege that Defendants committed fraud by carefully constructing parallel marketing structures designed to evade and circumvent the letter and spirit of the FDA's regulations. Because Parke-Davis was prohibited from promoting Neurontin for off-label uses, it created an "Off-Label Promotion Enterprise" that was comprised of the following three groups that shared the common purpose of promoting Neurontin for off-label uses:[8] (1) Defendants; (2) participating physician advocates; and (3) medical marketing firms. ACC, ¶ 41. Within the larger Off-Label Promotion Enterprise, two sub-enterprises were created, the Peer-Selling Sub Enterprise and the Publication Sub-Enterprise. ACC, ¶ 43.[9]

A. Peer Selling Sub Enterprise

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[8] The Coordinated Complaint asserts the common purpose of "aiding defendants in deceptively and fraudulently marketing Neurontin for off-label uses and achieving significant 'market expansion' for Neurontin." Coordinated Complaint, ¶ 38.

[9] The Coordinated Complaint alleges numerous "alternative parallel enterprises", consisting of: 1) Defendants; 2) one medical marketing firm; and 3) physician participants. Coordinated Complaint, ¶ 169.

Plaintiffs allege that Parke-Davis knew that physicians viewed promotional presentations by drug companies with caution, and that recommendations by fellow practitioners had greater influence on doctors' prescription writing behavior. With that in mind, Parke-Davis instructed its sales department to select doctors at major teaching hospitals to become "Neurontin experts" who would in turn deliver the "Neurontin message" to other physicians to boost sales of the drug.

In order to lure physicians to participate in the Peer Selling Sub-Enterprise, Parke-Davis approached target doctors and informed them of opportunities for research funds and clinical trials at their institutions. Doctors who were willing to speak favorably about Neurontin "could likely" receive substantial funds in the form of research grants. Defendants made outright payments, in the form of grants, to reward demonstrated Neurontin believers and advocates. ACC, ¶ 226. Plaintiffs provide a list of 11 grants, totaling $29,400.00, and allege that each of these grants constitutes a kickback for the recipient's advocacy of Neurontin. Id.

Parke-Davis drafted "tactical plans" that called for various medical marketing firms to produce hundreds of events, including continuing medical education seminars (CMEs), consultants' meetings, advisory boards, speakers' bureaus, teleconferences and dinner meetings at which the physician participants promoted the off-label use of Neurontin to thousands of attendee doctors who had no intention of prescribing Neurontin for adjunct epilepsy treatment. ACC, ¶ 53.

Plaintiffs identify eight medical marketing firms that were hired by Pfizer to coordinate the numerous meetings at issue. They contend that the CMEs were set up to appear to qualify for the exceptions to the FDA's off-label regulations that permitted physicians to learn about off-label uses at independent and educational seminars. The meetings at issue, however, were not

bona fide educational seminars. In reality, they were designed so that attendees would not receive fair and balanced information about Neurontin. ACC, ¶ 56. The defendants designed and approved the programs; handpicked the speakers; approved the presentations; selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin; and monitored the prescription patterns of the attendee physicians. ACC, ¶ 223. All of this was done to insure that the prescriptions of Neurontin for off-label uses would increase. Id.

After Defendants and the medical marketing firms worked together to determine the content of a particular program, the marketing firms submitted a proposal to Parke-Davis to fund these programs. The grants covered all expenses of producing the programs, including the participating vendors' fees and expenses, the speaking fees and travel expenses of the participating physicians,[10] payments to the accrediting institutions, costs incurred in hosting and producing the event, honoraria to be paid to the attending physicians, and in some cases, the attendees' travel, lodging, food and entertainment expenses. ACC, ¶ 53.

The false and fraudulent statements alleged are set forth below. For the most part, the Complaints generally describe rather than directly quote these statements, thus the following review of the statements necessarily does the same.

The following are statements allegedly made by doctors as part of the Peer Selling Sub Enterprise.

i. Statements Regarding Pain

[10] According to Plaintiffs, at least 28 individual physician participants each received $25,000 or more (exclusive of travel, food, lodging and entertainment benefits) for participating in the Off-Label Promotion Enterprise. One doctor, Dr. Joe Wilder, is alleged to have made $307,958. ACC, ¶ 104.

- Plaintiffs claim that at a consultants meeting in April of 1996 in Jupiter Beach, Florida, Dr. David Longmire said that Neurontin was effective for treatment of pain. He repeated the statement in May 1996 in Boston. ACC, ¶ 129.

- Also in May 1996, Dr. Steven Schacter said, "Pain specialists are finding that low dosages of Neurontin are effective." Id.

- "Comparable statements" were made by Dr. Bruce Nicholson in April, May, and June 1996. Id.

The ACC alleges that no clinical evidence to support these claims existed. ACC, ¶ 130.[11]

ii. Statements Regarding Restless Leg Syndrome

- "Physician participants" routinely stated that Neurontin is effective for the treatment of restless leg syndrome. Plaintiffs allege that in March 2000, (unnamed) speakers at a conference in San Antonio, Texas implied that clinical trial evidence existed to support such claims. ACC, ¶ 140.

However, Plaintiffs allege that clinical studies in existence did not find Neurontin to be effective for Restless Leg Syndrome. ACC, ¶ 141.

iii. Statements Regarding Bipolar Disorder

- "Physician speakers" routinely stated that Neurontin is effective for the treatment of bipolar disorder. ACC, ¶ 150.

Plaintiffs cite to 16 meetings between 1998 and 2000, for which they provide dates and locations. They do not, however, identify by name any person that spoke at those meetings. ACC, ¶¶ 152-154. They further allege that Parke-Davis knew as of 1997 that clinical evidence showed that Neurontin was not "significantly superior" to a placebo in treating bipolar disorder. ACC, ¶ 152.

iv. Statements Regarding Social Phobia

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[11] The reference to "clinical evidence" refers here, as it does throughout the Complaints, to data collected in clinical trial studies.

- Plaintiffs allege "upon information and belief" that (unnamed) physician participants "expressly stated or implied" that Neurontin was effective for the treatment of social phobia at 16 meetings between 1998 and 2000. Plaintiffs allege the date, time and place of these meetings. ACC, ¶157.

Plaintiffs claim that the only clinical study on Neurontin's efficacy for Social Phobia was inconclusive. ACC, ¶ 158.

v. Statements Regarding Panic Disorder

- Plaintiffs cite to 16 meetings held between 1998 and 2000 at which (unnamed) physician participants routinely stated that Neurontin was an effective treatment for panic disorder. Plaintiffs allege the date, time and place of these 16 meetings. ACC, ¶ 162.

According to Plaintiffs, clinical studies in existence did not find Neurontin to be more effective than a placebo for panic disorder. ACC, ¶ 164.

vi. Statements Regarding Migraine

- In May 1996, Parke-Davis held an advisory board meeting to discuss Neurontin and migraine management, at which it suppressed any reference to a "failed" migraine study. ACC, ¶¶ 174-177.

Plaintiffs assert that a clinical study showed that 900 mg of Neurontin was not statistically significant as compared to a placebo. ACC, ¶ 174.

vii. Statements Regarding Dose Dependency

- Plaintiffs allege that physician speakers routinely stated that dosages above the FDA 900 mg per day increased Neurontin's efficacy. Dr. Rafferty, a researcher from Parke-Davis, stated that "the anti-epileptic activity of gabapentin is quite dose dependent." ACC, ¶ 189.

- In April of 1996 at a conference in Jupiter Beach, Florida, Dr. Longmire stated that "most [patients] do better as you raise [the dose] higher." ACC, ¶ 190.

- Dr. Longmire also stated in May of 1996, "The problem with Neurontin in terms

of real trigeminal neuralgia is that it has to be titrated upward. And when I say 1500 mg, that's the target starting dose. There are colleagues in the Huntsville area who have people on 5400 with no side effects." ACC, at ¶ 192.

However, according to Plaintiffs, there was a lack of clinical data supporting Neurontin's use at higher doses. ACC, ¶ 193.

viii. Statements Regarding Diabetic Neuropathy

- At the April 1996 consultants meeting at Jupiter Beach, Dr. Bruce Nicholson stated that diabetic neuropathy patients "will" have their burning sensations relieved. In April of 1996 and October of 1998, "similar statements" were made. ACC, ¶ 135. The speakers are not identified.

Parke-Davis' own clinical study showed that Neurontin was not effective. ACC, ¶ 137.

ix. Statements Regarding Monotherapy

- Plaintiffs claim that Drs. Harden and LeRoy stated that Neurontin was effective for monotherapy for epilepsy at a conference in Jupiter Beach, Florida in August of 1996. ACC, ¶ 167.

Clinical studies failed to support a monotherapy indication. ACC, ¶¶ 168-169.

x. Statements Regarding Other Indications

- Plaintiffs allege that physician participants touted Neurontin as being effective for "other indications" in addition to those described above. ACC, ¶ 182.

The Complaints allege no further detail regarding these other allegedly false statements or the medical indications to which the statements relate.

Plaintiffs allege that any presenter who presented an unfavorable view of Neurontin was blacklisted from speaking at future events. For example, on June 23, 1997, the medical marketing firm Cline-Davis coordinated a CME "on behalf of" the American Diabetes Association. It became known to Cline-Davis that one of the speakers, who had been recommended by Parke-Davis, would describe negative results in her study of Neurontin's use

for an off-label indication. Cline-Davis planted a doctor in the audience to ask questions that led the presenter to make favorable statements during the question and answer period. Cline-Davis stated in a subsequent memorandum to Parke-Davis that it had a "policy to complete a literature search to determine who authors favorable articles on the topics outlined," and that "guidelines have been to [sic] set to ensure that this type of situation [a negative presentation] does not happen again." ACC, ¶ 63.

B. Publication Sub Enterprise Statements

In addition, Plaintiffs allege that numerous medical marketing firms assisted Defendants in causing a variety of articles touting Neurontin for off-label uses to be published in medical journals. Although articles had to appear as if they emanated from independent physicians who conducted independent investigations of Neurontin, Defendants decided what topics the papers would cover and paid all expenses for technical writers to draft the articles. ACC, ¶¶ 105-108. The articles were then submitted to a physician who "loaned" his or her name to the article in exchange for an honorarium.

Between 1997 and 1998, a firm known as MES prepared at least 12 different articles, mostly about off-label uses including pain, behavioral disorders, and migraine. ACC, ¶ 109. Another firm, AMM/Adelphi, was retained to prepare at least eight different case reports in 1996. Most of the articles that were developed by AMM/Adelphi related to pain, RSD[12], and restless leg syndrome. ACC, ¶ 110.

Plaintiffs allege that physicians who read the articles were led to believe that they were the independent, unbiased research of the physicians named as the authors of the articles.

[12] Plaintiffs do not identify "RSD".

Readers were not made aware of the fact that Defendants solicited the articles and paid significant sums of money to the physician authors to make favorable statements about Neurontin. ACC, ¶ 115. Plaintiffs allege that in cases where physicians wrote the articles themselves, if a physician wrote a negative article, Defendants either attempted to intervene and have a more favorable draft written, or did their best to suppress the article.

Plaintiffs allege three specific instances involving the misrepresentation of the results of a scientific study. ACC, ¶¶ 118-121, 145, 167. They also allege two instances in which articles failed to reveal that the author had received an honorarium paid by Defendants by way of one of the medical marketing firms ACC, ¶ 116.

C. Statements Made by Pfizer's Sales Representatives

Finally, Plaintiffs allege that Pfizer's own sales representatives, known as medical liaisons, made false and misleading statements to physicians regarding Neurontin's efficacy for off-label uses. Medical liaisons engaged in a full-scale effort to promote Neurontin's off-label uses by providing non-scientific, anecdotal information designed to convince physicians that off-label usage of Neurontin was safe and effective. ACC, ¶ 208. The strategy for the marketing was laid out by John Ford, a senior marketing executive at Parke-Davis, who instructed the sales representatives:

> I want you out there every day selling Neurontin. Look, this isn't just me, it's come down from Morris Plains that Neurontin is more profitable . . . we all know Neurontin's not growing adjunctive therapy, besides that's not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing . . . we can't wait for them to ask, we need to get out there and tell them up front . . . That's where we need to be holding their hand and whispering in their ear Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything . . . I don't want to see a single patient coming off

> Neurontin until they have been up to at least 4800 mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug.

Coord. Complaint at ¶ 33.

Plaintiffs allege that several "Verbatim Reports" indicate that Parke-Davis' medical liaisons made affirmative statements about Neurontin's efficacy. Apparently, as explained at oral argument by counsel, a Verbatim Report is an industry publication used to gauge and record physician's responses and impressions of a drug following a continuing medical education conference or seminar. Thus, doctor-attendees fill out the reports to record "verbatim" their thoughts and impressions of the drugs. At least as explained, they are not "verbatim" reports of statements made by the speakers at the conferences.

According to Plaintiffs, the Verbatim Reports state:

- An October 1995 Verbatim Report stated that Neurontin had received a "[n]ew indication for chronic pain." ACC, ¶ 134.
- A December 1995 Report reflected that Neurontin was a "[g]ood anti-convulsant for chronic pain and restless leg syndrome." Id.
- July 1996 Report indicated that it was "[e]ffective for many types of chronic pain." Id.
- December 1996 Report stated that Neurontin was "[g]ood for back pain; neuropathic pains." Id.
- Medical liaisons made representations, in 1997, August 1998, and December 1998 that Neurontin was "effective" for bipolar disorder. ACC, ¶ 156.
- Plaintiffs allege that in August 1996, a medical liaison stated that Neurontin was "effective in controlling . . . restless leg syndrome." ACC, ¶ 148.
- In December 1996, a medical liaison stated that Neurontin was "good for restless leg syndrome." Id.

- Plaintiffs allege "upon information and belief" that a review of recent Verbatim Reports demonstrates that Parke-Davis' medical liaisons routinely made false statements regarding the utility of Neurontin in treating migraine. The only statement cited by Plaintiffs is one made by an unnamed medical liaison in August 1996, who said that Neurontin was "[e]ffective in controlling. . .migraine headache." Id.

Plaintiffs allege no detail regarding the identity of the speaker, or when and where the statements were made.

D. Results of Defendants' Efforts

Plaintiffs allege that the Off-Label Promotion Enterprise created an explosion in the off-label use of Neurontin by artificially creating the perception that physicians were clinically using Neurontin and investigating its efficacy in off-label uses on their own initiative, rather than as a result of the illegal off-label marketing activities. ACC, ¶ 98. By 2003, ten years after its FDA approval, Neurontin generated $2.2 billion in annual revenue. ACC, ¶ 46. According to Plaintiffs, Pfizer achieved this staggering increase in revenue (from the initial estimate of $500 million over the drug's lifetime) not just by enlisting the aid of medical marketing firms and physicians to tout Neurontin's efficacy for off-label uses, but by doing so in a false and misleading manner.

III. DISCUSSION

A Complaint should not be dismissed under Fed.R.Civ.P. 12(b)(6) unless "it appears beyond doubt that the plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957). When reviewing a motion to dismiss, the Court must "accept the allegations of the complaint as true, and if, under

any theory, the allegations are sufficient to state a cause of action in accordance with the law, [the Court] must deny the motion to dismiss." Vartanian v. Monsanto Co., 14 F.3d 697, 700 (1st Cir. 1994)(citation omitted). The Court is to draw all reasonable inferences in the plaintiffs' favor. See Coyne v. City of Somerville, 972 F.2d 440, 443 (1st Cir.1992).

A. RICO Allegations

Plaintiffs allege that Defendants engaged in a pattern of racketeering activity by making fraudulent statements about the effectiveness of Neurontin through the use of interstate mails and wire communications in violation of 18 U.S.C. § 1962 (c). To state a successful RICO claim, a plaintiff must allege four elements: "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985).

Defendants have moved for dismissal of the RICO claims on the following grounds: (1) that Plaintiffs fail to allege that Defendants acted with scienter; (2) that Plaintiffs fail to plead facts establishing causation; (3) that Plaintiffs fail to allege a cognizable injury; (4) that Plaintiffs fail to adequately allege RICO enterprises; (5) that Plaintiffs have not adequately alleged that Defendants had the requisite control over the alleged enterprises; (6) that Plaintiffs have failed to plead predicate acts of mail or wire fraud. I will address these arguments in order.

1. Scienter

Pursuant to Fed.R.Civ.P 9(b), scienter may be averred in general terms. See Rodi v. Southern New England School of Law, 389 F.3d 5, 15 (1st Cir.2004). Defendants argue that the only fact alleged in support of Plaintiffs' "conclusory" scienter allegations is that Defendants were motivated by money. However, Plaintiffs have alleged that Defendants intentionally

created a marketing structure to fraudulently promote Neurontin for off-label uses. They have also alleged that Defendants concealed negative studies and lied about the results of negative studies in order to increase prescriptions. This suffices for pleading Defendants' scienter at this stage in the proceedings.

With regard to the medical marketing firms, Plaintiffs have alleged that they knew that their final products were biased, and that in fact they intentionally created their programs so as not to be fair and balanced. ACC, ¶ 56. However, while Plaintiffs may have adequately alleged that the medical marketing firms intended to evade FDA regulations to promote Neurontin for off-label purposes, they have not alleged that the medical marketing firms knew or intended that fraudulent statements were made in the marketing campaign. Plaintiffs have not alleged scienter on the part of the medical marketing firms.

Also notably absent are allegations that the physician speakers knew that they were presenting false or misleading information. During oral argument, Plaintiffs argued that some, but not all, doctors knew that they were making false statements. They offered no facts to support this allegation. In addition, in their Opposition to Defendants' Motion to Dismiss, Plaintiffs argued that the physicians "knowingly" touted Neurontin, and that the technical writers "knowingly" wrote articles touting Neurontin. An allegation that a doctor knew that she was touting Neurontin is altogether different from an allegation that she knew that what she was saying was fraudulent. Although scienter may be averred generally, there is no basis from which one can infer scienter on the part of the physicians, nor is there a direct allegation that the doctors made the statements with the requisite state of mind.

Alternatively, Plaintiffs argue that it is immaterial whether the doctors consciously misled

their captive audiences, or were themselves duped by the defendants. This argument poses a critical question: that is, whether Defendants can be held responsible for the statements of the doctors. See discussion of this issue, *infra*. Even if defendants are responsible for the physicians' statements, however, that does not establish the physicians' scienter. For that reason, Plaintiffs have failed to plead scienter on the part of the physician participants.[13]

2. Causation

Defendants argue that Plaintiffs fail to plead causation because they do not allege facts demonstrating a link between the conduct alleged and the payments for Neurontin. Plaintiffs, on the other hand, argue that a reasonable inference can be drawn that connects the fraudulent scheme to the writing of prescriptions. They assert that sales of Neurontin increased from $97.5 million in 1995 to $2.7 billion in 2003, with 90% of the prescriptions written for off-label uses. ACC, ¶ 46. Defendants respond with an interesting argument that causation can not be proved by a "fraud on the market" theory. See Heindel v. Pfizer, 381 F.Supp.2d 364, 380-81 (D.N.J.2004). However, it is not necessary to undertake such an analysis at this stage in the proceedings because Plaintiffs have sufficiently pled causation.

The same common law tort principles that Judge Saris described in United States ex rel Franklin, 2003 WL 22048255 at *11 (D.Mass. Aug. 22, 2003) are applicable to the instant matter.

> Causation in tort law is generally divided into two concepts: causation in fact, or actual causation, and proximate or legal causation. . .there are two questions that must be answered to determine if a defendant's conduct 'caused' a plaintiff's

[13] The issue on whether the medical marketing firms and physicians (both non-parties) acted with scienter bears on whether an enterprise existed between Defendants and these two groups.

> injury. The first question is whether there was in fact some causal relationship between the conduct and the outcome. The *Restatement* expresses this test as whether the defendant's conduct was a 'substantial factor' in producing the harm. The second question is whether the circumstances and causal relationship are such that the law will impose liability on the defendant. Sometimes this is expressed as a foreseeability test." Id., citing Rodriguez-Cirilo v. Garcia, 115 F.3d 50, 54 (1st Cir.1997)(Campbell, J., concurring)(internal citations omitted).

Defendants, citing Holmes v. Securities Investor Protection Corp., 503 U.S. 258, 266 n. 11 (1992), assert that a "heightened" standard applies to pleading causation under RICO. However, in the footnote defendants cite, the Supreme Court did not establish a "heightened" pleading requirement; rather, it noted that the "Courts of Appeals have overwhelmingly held that not mere factual, but proximate, causation is required." Id. Nonetheless, the First Circuit has ruled that "a greater level of specificity is required in RICO," Bessette v. Avco Fin. Servs., Inc., 230 F.3d 439, 443 (1st Cir.2000), citing Garita Hotel Ltd. P'ship v. Ponce Fed. Bank., 958 F.2d 15, 17 & n. 1 (1st Cir.1992). Plaintiffs are required to "state facts sufficient to portray . . . a causal nexus between [the alleged racketeering activity] and the harm alleged." Miranda v. Ponce Federal Bank, 948 F.2d 41, 44 (1st Cir.1991). Thus, Plaintiffs must show that their "injuries were caused by the predicate acts of wire and mail fraud." Efron v. Embassy Suites (Puerto Rico), Inc., 223 F.3d 12, 17 (1st Cir.2000). Plaintiffs have sufficiently established causation for present purposes of the motion to dismiss.

Defendants' actions were a substantial factor in causing the prescription of Neurontin. Plaintiffs have alleged detailed facts regarding a large scale coordinated effort to market Neurontin for off-label uses over a substantial period of time with resulting success in the form of increasing off-label prescriptions for Neurontin. They further allege that the fraudulent, false

and misleading statements made during the campaign caused the significant increase in sales.[14] Plaintiffs have not pled causation prescription by prescription. While they cannot, and do not, proceed on a fraud on the market theory (see Plaintiffs' Joint Opposition to Defendants' Motion to Dismiss, at 13), they have alleged enough detail to establish at this stage that Defendants' challenged conduct was a substantial cause of prescriptions written by physicians and paid for by Plaintiffs. Specifically, Plaintiffs allege that physicians relied upon the statements, that Defendants targeted prescribers of Neurontin; and that Defendants monitored and measured the effects of the successful campaign. ACC, ¶¶ 216, 219, 223, 249. This is sufficient for present purposes, as it gives rise to the inference that Defendants' actions caused or contributed to the increase in prescriptions. See United States ex rel Franklin, 2003 WL 22048255 *5 (finding that evidence of increasing rate of prescriptions after conferences, coupled with evidence of listeners' state of mind afterward, sufficed to create triable issue on causation). Obviously, Plaintiffs bear the burden of proving this link in more detail at later stages of the case. The named plaintiffs, for example, will need to establish that their physicians prescribed Neurontin as a result of Defendants' fraudulent or misleading statements. See In re Rezulin Prod. Liability Litig., 210 F.R.D. 61, 68 (S.D.N.Y.2002). While, as Defendants point out, other facts may explain the significant rise in sales, before the Court is a Motion to Dismiss, and the specific facts plaintiffs have alleged do "portray" in sufficient detail the causal connection to satisfy the standard for pleading causation under RICO.

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[14] Plaintiffs also allege that the deceptive nature of the campaign, in violation of various FDA regulations, also caused the increase in sales. Because I find that Plaintiffs' attempts to enforce the FDA regulations are preempted, I do not recommend relying upon the foregoing assertion for the causation analysis.

Plaintiffs also sufficiently allege that Defendants' actions constitute a proximate cause of the prescription of Neurontin. They convincingly argue that the writing of prescriptions was not only foreseeable, but was the intended consequence of the alleged scheme to defraud. See Franklin, 147 F.Supp.2d at 52-53. Defendants' argument that prescribing physicians constitute an "intervening cause," thereby disrupting the chain of causation, is unpersuasive for the same reasons enunciated by Judge Saris in Franklin. "Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of the doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." Id. at 52-53. The same applies here to the writing of, and payment for, Neurontin prescriptions.

Defendants' argument that the third party payors (TPPs) have failed to plead causation because any injury suffered by them is too remote is likewise without merit and does not warrant lengthy discussion. See In re Pharmaceutical Industry Avg. Wholesale Price Litig., 307 F.Supp.2d 196, 207 (D.Mass.2004)("The Defendants' arguments are not persuasive. In the private, end-payor context, the harm alleged by Defendants' alleged actions is visited directly upon the end-payor Plaintiffs, as they have paid directly for the named drugs . . ."); see also In re Lupron Marketing and Sales Practices Litig., 295 F.Supp.2d 148, 175 (D.Mass.2003)(Stearns, J.) (finding that a similar argument "borders on the frivolous" because it "ignores . . . the corollary requirement that the intervening act be unforeseeable and completely independent of any act undertaken by the original actor").

3. Cognizable Injury

Defendants argue that Plaintiffs do not allege an actual loss because they do not claim that any of them suffered a personal injury as a result of taking Neurontin; rather, they seek recovery only for economic losses. However, although Defendants contend that Plaintiffs do not allege that Neurontin failed to perform as expected, the Class Plaintiffs have alleged that Neurontin is ineffective in treating the off-label conditions for which it was prescribed. ACC, ¶ 249. Indeed, Plaintiffs claim that they received no greater relief from, or treatment of, their medical conditions than they would have received from a placebo. (Id.). They argue that Defendants fraudulently induced doctors to prescribe higher doses of Neurontin, and that they were damaged economically because they paid for Neurontin that, but for Defendants' fraud, they would never have purchased.

Defendants are correct to argue that Plaintiffs need to allege an actual loss in order to state a claim. See In re Rezulin, 210 F.R.D.at 68. For present purposes, the Class Plaintiffs have sufficiently alleged injury as they claim that Neurontin was ineffective for the conditions for which it was prescribed. Therefore, they did not receive the benefit that they paid for after being induced to do so by the alleged fraud. See Desiano v. Warner-Lambert, 326 F.3d 339, 349 (2nd Cir.2003)(sustaining a cause of action based on the allegation that "fraud directly caused economic loss to [Plaintiffs] as purchasers, since they would not have bought Defendants' product . . . had they not been misled by Defendants' misrepresentations").

However, the result is different with respect to the Coordinated Complaint. In response to Defendants' argument that Plaintiffs have not alleged that Neurontin was ineffective, the Coordinated Plaintiffs cite to several paragraphs in their Complaint that they contend do so plead. For example, ¶ 249 of the Coordinated Complaint asserts that "Defendants' scheme and the

above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was *not proven* to be safe and efficacious, effective and useful."(emphasis added). See also ¶ 2 ("Defendants systematically . . . created a pervasive, fraudulent and unlawful system to cause insurers and individual patients to pay for Neurontin to treat a variety of symptoms for which Neurontin had not received approval from the FDA, and for which the drug was *not proven* to be safe, medically efficacious, effective or useful."); ¶ 29 ("No clinical trial showed that Neurontin was safe or effective for any of these conditions") ; ¶ 162 ("[n]o clinical evidence supported Neurontin's efficacy at dosages greater than 1800 milligrams per day"); ¶ 183 ("the fraudulent scheme was designed to, and did, cause plaintiffs to pay for Neurontin prescriptions to treat conditions for which the drug is not proven to be medically safe, efficacious, effective, or useful.").

Plaintiffs' contention that it is sufficient to argue that they paid for a drug that "had not been proven effective" is without merit. It is simply not enough to claim that Neurontin had not been proven to be effective; rather, Plaintiffs must allege that it was ineffective. "Without alleging that a product failed to perform as advertised, a Plaintiff has received the benefit of his bargain and has no basis to recover purchase costs." Williams v. Purdue Pharma Co., 297 F.Supp.2d 171, 176 (D.D.C.2003)(citation omitted). The only allegation in the Coordinated Complaint that even approaches an allegation of ineffectiveness is found in ¶ 123 ("The program did not inform attendees of the unfavorable clinical trials that found that Neurontin was not effective for bipolar disorder"). Therefore, the Coordinated Plaintiffs, in contrast to the Class Plaintiffs, have failed to allege a cognizable injury.

4. RICO Enterprise

Under the RICO statute, the term "'enterprise' includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961 (4). The existence of an enterprise is "proved by evidence of an ongoing organization, formal or informal, and by evidence that various associates function as a continuing unit." United States v. Turkette, 452 U.S. 576, 583 (1981). Importantly, an enterprise must be "an entity for present purposes a group of persons associated together for a *common purpose* of engaging in a course of conduct." Id. (emphasis added). "[F]ailure to identify any enterprise, distinct from a named person defendant, is fatal under RICO." Doyle v. Hasbro, Inc., 103 F.3d 186, 191 (1st Cir.1996).

In the instant matter, Plaintiffs allege the existence of several "associations in fact." The First Circuit has held that in order to prove the existence of an association in fact, a plaintiff must show that the various allegedly associated groups "constitute a larger unit, over and above their separate structures and operations." Libertad v. Welch, 53 F.3d 428, 442 (1st Cir.1995).

The First Circuit has identified six-factors to aid in the determination of whether an alleged association-in-fact meets RICO's heightened pleading requirements: "(1) whether the associates have a common purpose; (2) whether there is systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination; (3) whether there is a common communication network for sharing on a regular basis; (4) whether the associates hold meetings and sessions where important discussions take place; (5) whether the associates wear common colors, signs or insignia to make the group identifiable; and (6) whether the group conducted common training and instruction." In re Pharm. Indus. Avg. Wholesale Price Litig., 307 F.Supp.2d at 203-204 (citations omitted). A plaintiff must also allege that each of the alleged

participants knew of the fraudulent nature of the enterprise. Id. at 204.

As discussed above, Plaintiffs allege an Off-Label Promotion Enterprise that consisted of two Sub-Enterprises, the Peer Selling Enterprise, and the Publication Enterprise.[15] According to Plaintiffs, both of the Sub-Enterprises had the same structure. They consisted of (1) Parke Davis; (2) medical marketing firms who appeared independent and separate from Parke Davis; and (3) physician spokespersons.

Here, Plaintiffs do not cite facts sufficient to support an allegation that the physician participants and/or the medical marketing firms knew of the fraudulent nature of the statements. While the common purpose may have been to promote the off-label prescriptions of Neurontin, this is not actionable. The lack of a common purpose with an intent to defraud is fatal to Plaintiffs' claims of enterprise. The common purpose must be to promote Neurontin for off-label uses *through the use of making false and misleading statements.* See Bonilla v. Volvo Car Corp., 150 F.3d 62, 73 (1st Cir.1998) (rejecting inference of intention to promote fraud by Volvo absent Volvo's knowledge of its co-defendants' fraud). "The participants, as described, do not share a common purpose more specific than that common to many human endeavors, the reaping of a profit . . . without a shared illegal purpose to defraud, the shared innocent objective . . . would not support a claim of a RICO enterprise." In re Pharm. Indus. Avg. Wholesale Price

[15] In the alternative, Plaintiffs assert that each of the sub-enterprises is in and of itself an association in fact. In another alternative, Plaintiffs assert that each sub-enterprise could consist solely of the vendor participants and Defendants, without the presence of the physicians. ACC, ¶ 275. In yet another alternative, Plaintiffs assert that the sub-enterprises can be broken down into further, smaller enterprises comprised of one vendor from either the peer selling sub-enterprise or the publication sub-enterprise, along with Defendants, and the participating physicians. ACC, ¶ 276. And in a final alternative, Plaintiffs allege that the smaller enterprises can be comprised only of an individual vendor and the Defendants, without the participating physicians. Id. None of these variations resolves the problems discussed in the text.

Litig., 307 F.Supp.2d at 204-205.

There is no allegation of a global agreement between Defendants and the medical marketing firms and physicians. Rather, individual agreements between Defendants and the individual physician participants and firms are alleged. While Plaintiffs have identified 28 physician participants, there are also numerous unnamed physicians who presumably are alleged to have spoken at the large number of meetings. In addition, there are approximately ten medical marketing firms identified. Plaintiffs have offered no facts to indicate that any of these people were working together as part of a cohesive group. Thus, they have failed to allege how this "large and geographically diverse group of . . . independent physicians and entities acted in concert with one another . . . there is no indication that the individual [providers] were even aware of each other's existence." In re Pharm. Indus. Avg. Wholesale Price Litig., 263 F.Supp.2d 172,183 (D.Mass.2003)(Saris, J.), quoting Blue Cross of Cal. v. SmithKline Beecham Clinical Labs, Inc., 62 F.Supp.2d 544, 551-553 (D.Conn.1998).

Here, Plaintiffs have described a scenario whereby Pfizer, at the center, deals independently with each medical marketing firm and physician participant as a "spoke." This arrangement, in Supreme Court vernacular, is a "hub-and-spoke" assemblage of a conspiracy, which is disfavored. See In re Pharm. Indus. Avg. Wholesale Price Litig., 263 F.Supp.2d at 183; In re Lupron, 295 F.Supp.2d at 174 n. 29.

According to Plaintiffs, Defendants maintained "systematic linkages" between themselves and the medical marketing firms, including continuing coordination between their respective marketing teams. While Plaintiffs have arguably sufficiently alleged systematic linkages between Defendants and one medical marketing firm, Physicians World, they have not

done so with respect to the other marketing firms. With regard to Physicians World, Plaintiffs allege that in December 1995, Parke-Davis formed a "strategic partnership" with Physicians World to handle the various promotional events. According to a memorandum issued by Larry Perlow, Parke-Davis' vice president of Portfolio Management, Parke-Davis and Physicians World would commingle employees, and, in January 1996, Parke-Davis' Marketing Support Staff jointed Physicians World as full-time employees. Those employees continued to use the same toll free 800-numbers that they had used at Parke-Davis, and they also utilized Parke-Davis letterhead. With these allegations, Plaintiffs have sufficiently pled "systematic linkages" between Defendants and Physicians World; however, this does not correct the deficiency in the remainder of their RICO Enterprise allegations.

Finally, the First Circuit has consistently held that the same entity "cannot do double duty as both the RICO defendant and the RICO enterprise." Miranda v. Ponce Federal Bank, 948 F.2d at 44-45. Accordingly, Defendants cannot constitute an enterprise on their own. Plaintiffs have failed to plead a RICO enterprise.

5. Control

Defendants argue that Plaintiffs have failed to plead with heightened particularity that Defendants controlled the alleged RICO enterprises. The Supreme Court has rejected the proposition that Section 1962(c) requires "*significant control* over or within an enterprise." Reves v. Ernst & Young, 507 U.S. 170, 179 n.4 (1993) (emphasis supplied). Rather, *some* level of participation and direction is required. "In order to 'participate, directly or indirectly, in the conduct of such enterprise's affairs,' one must have some part in directing those affairs. Of course, the word 'participate' makes clear that RICO liability is not limited to those with primary

responsibility for the enterprise's affairs, just as the phrase 'directly or indirectly' makes clear that RICO liability is not limited to those with a formal position in the enterprise, but *some* part in directing the enterprise's affairs is required." Id. at 179 (emphasis supplied).

Here, Plaintiffs have alleged that Defendants controlled the content of the physician statements at each seminar, handpicked the speakers, selected the attendees for each seminar, and paid the medical marketing firms and physician participants. While Defendants correctly argue that Plaintiffs' failure to identify specific instances of conduct renders the majority of allegations conclusory, this is not fatal to Plaintiffs at this stage of the proceedings. Plaintiffs have alleged with sufficient specificity that Defendants paid physicians to speak at the seminars. They have provided a list of physicians, as well as the amount of money paid to each. In addition, they have alleged that medical marketing firms reported to Defendants about the seminars. This is sufficient to show that Defendants had "some part in directing" the affairs of the enterprise. For present purposes, Plaintiffs have adequately alleged control.

6. Predicate Acts

Pursuant to Fed.R.Civ.P. 9(b), the First Circuit requires specificity in the pleading of mail and wire fraud under RICO. See New England Data Services, Inc. v. Becher, 829 F.2d 286, 290 (1st Cir.1987). A RICO plaintiff must state "the time, place and content of the alleged mail and wire communications" perpetrating the fraud. Id. Here, the extent of plaintiffs' allegations are as follows:

> The planning and coordination of all of these events by the third party medical marketing firms required extensive use of the wires and mails, including the mailing of invitations to physicians, the mailing of proposals to the accrediting institutions, booking of hotels and airline tickets, the arrangement of meals, the scheduling of teleconference calls, the

development and modification of the tactical plans, and the coordination of the content of the presentations on Neurontin to be presented at the event. ACC, ¶ 58.

These general allegations clearly are insufficient to meet Rule 9(b)'s pleading standards. See Giuliano v. Fulton, 399 F.3d 381, 388-389 (1st Cir.2005)(finding predicate acts were pled insufficiently when "the most we are told is that '[t]he arrangements for the Arizona meeting . . . the agreements calling for [Defendants] to provide financing in furtherance of the Illegal Scheme, and the actual transfer of the funds [Defendant] provided for the financing were all accomplished through the use of mail and interstate wire communications . . . [and] . . . on multiple occasions on and after December of 1999, [Defendant] consulted and communicated by mail, telephone, and interstate wire transmission with the other participants in the Illegal Scheme, to discuss the planning and to make decisions about the method and strategy of carrying out the Illegal Scheme. These vague allegations do not satisfy Fed.R.Civ.P. 9(b).")

Here, Plaintiffs have pled the predicate acts in a similar manner to those pled in Giuliano. Therefore, they have not identified the predicate acts with sufficient particularity. Undoubtedly, Plaintiffs can be cure this deficiency after discovery, as it is likely that most of the information regarding the use of mail and wires is in the exclusive possession of the defendants. See id. Acknowledging the difficulties with pleading mail and wire fraud with the requisite specificity, the First Circuit provides that "[i]n an appropriate case, where, for example the specific allegations of the plaintiff make it likely that the defendants used interstate mail or telecommunications facilities, and the specific information as to use is likely in the exclusive control of the defendant, the court should make a *second* determination as to whether the claim as presented warrants the allowance of discovery and if so, thereafter provide an opportunity to

amend the defective complaint." Becher, 829 F.2d at 290 (emphasis supplied).

While application of this approach "is neither automatic, nor of right, for every plaintiff," North Bridge Assocs., Inc. v. Boldt, 274 F.3d 38, 44 (1st Cir.2001), quoting Ahmed v. Rosenblatt, 118 F.3d 886, 889-890 (1st Cir.1997), I would recommend` permitting this approach in the future if Plaintiffs otherwise plead their RICO claims sufficiently. This is especially so in light of the fact that "[i]n this day and age, it is difficult to perceive how the Defendants would have communicated without the use of the mail or interstate wires." In re Lupron, 295 F.Supp.2d at 171.

For all of the foregoing reasons, I recommend that the RICO claims be dismissed.

B. Section 1962(d) RICO Conspiracy

The pertinent portion of Section 1962(d) provides that it is unlawful to conspire to violate any of the provisions of Section 1962(c). See 18 U.S.C. § 1962(d). To state a claim under § 1962(d), a plaintiff must show (1) the existence of an enterprise; (2) that the defendant knowingly joined the enterprise; and (3) that the defendant agreed to commit, or in fact committed, two or more predicate acts as part of his participation in the enterprise. Libertad v. Welch, 53 F.3d at 441, quoting United States v. Anguilo, 847 F.2d 956, 964 (1st Cir.1988), *cert. denied* 488 U.S. 852 (1988).

Because I have already found that Plaintiffs have failed to establish the existence of an enterprise, the conspiracy claim necessary fails. "[I]f the pleadings do not state a substantive RICO claim upon which relief may be granted, then the conspiracy claim also fails." Efron v. Embassy Suites (Puerto Rico), Inc., 223 F.3d at 20.

C. State Law Claims

The ACC asserts a New Jersey Consumer fraud claim and a Massachusetts common law fraud claim (Counts III & IV). The Coordinated Complaint asserts similar claims under the laws of every state, Puerto Rico and the District of Columbia.

1. Preemption

Defendants argue that all of Plaintiffs' state law claims are preempted. At the outset, it should be noted that Plaintiffs complain of two general categories of misleading statements. Each category will be discussed individually.

a. Structure of the Marketing Campaign

First, Plaintiffs contend that Defendants designed the structure of the off-label marketing campaign in such a way as to conceal their involvement in the promotion of Neurontin. Along a similar vein, Plaintiffs claim that Defendants failed to disclose that virtually all publications and studies that supported off-label uses had been financed or subsidized by Defendants. In essence, physician attendees received an "infomercial" rather than scientific information. ACC, ¶ 99. According to Plaintiffs, actions taken to hide Defendants' control of the content of the program and misrepresent their financial support as an "unrestricted" grant were materially false statements. ACC, ¶ 206. Plaintiffs reason that had the attending physicians known that the programs were "outright promotion," they would have viewed the presentations with greater skepticism and doubted the claims of the participating physicians that Neurontin was effective for the off-label indications. Id.

With the above assertions, Plaintiffs complain of a campaign to market Neurontin for off-

label purposes both in violation of FDA rules prohibiting defendants from such activity and in violation of the FDA's "safe harbor" rules defining the conditions under which Defendants may disseminate information about potential off-label uses of Neurontin.

The FDA has adopted specific regulations governing off-label marketing of prescription drugs. The Food and Drug Administration and Modernization Act (FDAMA), 21 U.S.C. § 360aaa, *et seq*., and the "Guidance for Industry: Industry-Supported Scientific and Educational Activities" issued by the FDA (the "CME Guidelines") both set limits on a drug manufacturer's ability to promote drugs for off-label uses. The FDAMA, enacted in 1997, provides conditions under which a drug manufacturer will be permitted to distribute written information about a drug for off-label use. See Washington Legal Foundation v. Friedman, 13 F. Supp.2d 51, 58 (D.D.C. 1998)(reversed on other grounds). The CME Guidelines were instituted in response to concern about the promotional practices of drug manufacturers, see id. at 57, and set forth twelve factors used to determine whether seminars and symposia were "independent from the substantive influence of the supporting company, and therefore not subject to regulation, as opposed to when the manufacturer is in a position to influence the presentation of the information, or otherwise transform an ostensibly independent program into a promotional vehicle." Id. (internal citation and quotation marks omitted).[16]

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[16] The twelve factors include: "who controls the content and selects presenters and the moderator; whether there is meaningful disclosure as to the company's funding and whether unapproved uses will be discussed; the focus of the program, such as whether the central theme is on one product; the relationship between supporting companies and the CME provider; audience selection; opportunities for meaningful discussion and questioning; dissemination of information; ancillary promotional activities; and any complaints raised by the provider, presenters or attendees regarding attempts by the supporting company to influence content. Additionally, while not required, a written agreement between the provider and the supporting company can

A manufacturer who violates the provisions of the FDAMA or the CME Guidelines may be prosecuted by the FDA, not pursuant to an independent power created in the FDAMA or the CME Guidelines, but pursuant to its misbranding enforcement power set forth in the FDCA.[17] See Washington Legal Foundation v. Henney, 128 F.Supp.2d 11, 13 (D.D.C.2000).

Nonetheless, Plaintiffs never cite the applicable FDA regulations in the Complaints, (though they liberally use relevant terminology from the regulations), nor do they assert a claim directly for violating the FDA regulations. This is unsurprising in light of the fact that the FDCA vests exclusive enforcement authority with the FDA. Pursuant to the statute, "[Except for provisions for state action not applicable to the instant matter], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States . . ." 21 U.S.C. § 337(a). Thus, there is no federal private cause of action for a violation of the regulations. See also Buckman, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a) and stating "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"). See also Eli Lilly & Co. v. Roussel Corp., 23 F.Supp.2d 460, 476 (D.N.J.1998)(collecting cases and noting that "[e]very federal court that had addressed the issue has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions and accompanying

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provide valuable evidence as to whether an activity is independent and non-promotional. This written agreement is intended to demonstrate that the sponsoring company has no involvement in the CME seminars such that it might influence the content, and that the provider is solely responsible for designing and conducting the activity." Washington Legal Foundation, 13 F. Supp.2d at 57-58.

[17] Under the FDCA, a drug manufacturer is prohibited from introducing into interstate commerce a "misbranded" drug. See 21 U.S.C. § 331(a). A drug may be deemed misbranded if its labeling is "false and misleading in any particular." 21 U.S.C. § 352(a).

regulations.")

Notwithstanding the foregoing, Plaintiffs seek to enforce the FDCA and its accompanying regulations. For example, Plaintiffs allege that "Under the Food Drug and Cosmetic Act, and the regulations promulgated thereunder, all information provided by a drug company about its products, whether on or off-label, whether directed at consumer or physicians, must be fair and balanced." ACC at ¶ 32. Plaintiffs repeat this "fair and balanced" allegation throughout the Complaints. See, e.g., ACC at ¶¶ 38, 39, 56, 73, 124, 126, 128, 133, 139, 146, 147, 151, 155, 159, 161, 163, 165, 180, 182, 191, 197, 203- 205, 284. As Plaintiffs allege, the source and definition of this duty comes from the FDA regulations. See, e.g., 21 CFR § 202.1(e)(6) (prohibiting promotional material which is "false, lacking in fair balance, or otherwise misleading").

Defendants argue that Plaintiffs' state law claims are pre-empted because they conflict with federal law, and "stand[] as an obstacle" to the purposes of the FDCA. See Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Notwithstanding Congress' decision to vest exclusive authority to enforce the FDCA and its implementing regulations with the FDA, Plaintiffs contend they may enforce these federal substantive standards through state law causes of action. Plaintiffs rely upon a recent Supreme Court decision that permitted a state law tort suit enforcing a federal requirement to proceed, thereby providing the plaintiff with a state law damage remedy when none existed under the federal statute. See Bates v. Dow Agrosciences, LLC, 544 U.S. - -, 125 S.Ct. 1788, 1800-1801 (2005).

However, the Supreme Court's decision in Bates turned on the text and history of the

Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136, *et seq*. (FIFRA), which differs fundamentally from that of the FDCA, the statute at issue in the instant matter. See Bates, 544 U.S.- -, 125 S.Ct at 1793 ("The question presented is whether . . . FIFRA preempts [plaintiffs] state law claims for damages"). In contrast to FIFRA, the FDCA, by express command, clearly centralizes all enforcement in the FDA. See 21 U.S.C. § 337(a). FIFRA contains no such command. That Congress expressly imbued the federal government with the exclusive right to bring suit for violations of the FDCA has been a factor in determining whether state law claims will be preempted. See In re Pharm. Indus. Avg. Wholesale Price Litig., 321 F.Supp.2d 187, 199 (D.Mass.2004)(Saris, J.), in which the Court held that state law claims were not preempted by the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8. ("[I]n Buckman, Congress provided expressly that it was the federal government, not private litigants, that was authorized to file suit for non-compliance, whereas here the statute provides that the federal remedies are 'in addition to other penalties as may be prescribed by law'"). In contrast, the instant matter, like Buckman, involves the FDCA, which expressly provides that only the federal government may file suit for non-compliance.

The FDA's view on the reach, and limits, of its own authority bears on the interpretation and enforcement of the rules. The FDA's resolution of the foregoing involves some measure of discretion balancing the various competing concerns. The question of where and how to draw the foregoing lines belongs to the FDA, as the matter concerns its own authority. That Congress chose to vest exclusive enforcement jurisdiction in the FDA and, expressly, precluded a private right of action under the statute only further buttresses the conclusion.

In the present case, the fraud claims based upon the structure of the off-label marketing

campaign "exist *solely by virtue* of the FDCA disclosure requirements," Buckman, 531 U.S. at 353 (emphasis added), and accordingly are preempted. *Cf.* Medtronic, Inc. v. Lohr, 518 U.S. 470, 491 (1996)(rejecting preemption when claims arose from failure to use reasonable care in production in violation of state common law duty as well as from an FDCA violation).

b. Actual Statements Regarding Neurontin's Effectiveness

Defendants' contention that federal law preempts all of the state law claims is incorrect. According to Plaintiffs, those statements concerning the structure of the off-label campaign are "not the core of the wrongs alleged in the Complaints." (Plaintiffs' Joint Surreply, at 26). Rather, Plaintiffs focus on the allegedly fraudulent, false and misleading statements made by (or caused to be made by) Defendants in the course of the off-label marketing campaign described in the complaints. A preemption analysis *vis-a-vis* the statements necessarily differs from an analysis regarding the structure of the marketing campaign. This is so because the claims based on the statements arise not out of a violation of a federal regulation or law, but from state anti-fraud statutes or a common-law duty of truthfulness. Insofar as Plaintiffs seek to enforce state law duties of honesty or truthfulness, rather than duties created by the FDA's regulations, the state law claims may proceed.

Absent an express preemption provision, there is a strong presumption against federal preemption of state law claims. See In re Pharm. Indus. Avg. Wholesale Price Litig., 263 F.Supp.2d at 187. "Because the presumption against preemption applies, Defendants must show that there manifestly and clearly is an actual conflict between the state claims and the federal statute, and that any impediment is severe, not merely modest." In re Pharm. Indus. Avg.

Wholesale Price Litig., 321 F.Supp.2d at 199 (internal citations and quotation marks omitted).

Defendants rely principally on Buckman to support their contention that Plaintiffs' state law claims are preempted.[18] Buckman, however, is a "fraud on the agency" decision that courts have read narrowly, and applied mostly in the context of claims of fraud on the agency. See In re Lupron, 295 F.Supp.2d at 179 n.33. In the Complaints, Plaintiffs claim that Defendants made false and misleading statements, not to a federal agency, but to them, their doctors, or their insureds. Although it does not carry the weight of precedential authority, the reasoning of a recent case is persuasive: "Although Buckman precludes a plaintiff from seeking damages because the defendant lied to the FDA, it is something completely different to contend that plaintiff is precluded from seeking damages for injuries due to lies to her. Notwithstanding that information may have [been] misrepresented to or concealed from the FDA, once defendant undertook to misrepresent those facts to plaintiff, or to conceal from plaintiff facts it was bound to disclose, the plaintiff's claim no longer rests simply on the assertion that the agency was defrauded but on the additional fact that she was defrauded." Eve v. Sandoz Pharm Corp., 2002 WL 181972 at *2 (S.D.Ind. Jan. 28, 2002)(citation omitted). Plaintiffs in the instant matter are merely seeking to enforce the rights of states to curb deceptive business practices. The allowance

[18] Defendants note that under Buckman, there must first be in place a federal statutory scheme pursuant to which a federal agency is empowered to punish and deter the conduct at issue. Id. at 348. Second, preemption is called for if "a delicate balance of statutory objectives" would be skewed by allowing the state law claims to continue. Id. Finally, the state law claims must rely on a violation of federal law as a critical element of the case. Id. at 353. Although the first criteria of Buckman is clearly met, as the FDA "is empowered to investigate suspected fraud, and citizens may report wrongdoing and petition the agency to take action," id. at 349, applying the second and third criteria counsels against preemption. Because the claims rest on violations of long standing state law duties, the claims neither skew the "delicate balance of statutory objectives" nor assert a violation of a federal law or regulation as a critical element.

of a state law anti-fraud claim to proceed would not interfere with the FDA's regulation.

Here, Plaintiffs state law claims are based on duties arising under state law to refrain from deceptive business practices. An attack on a statement as being false and misleading stems from a duty to not commit fraud, rather than from a violation of any federal statute or regulation. Thus, Plaintiffs' claims are not preempted, to the extent that they attack the actual statements.

2. Pleading Fraud with Particularity

Plaintiffs allege that various fraudulent statements were made during the course of the promotion campaign. Defendants maintain that the statements are non-actionable because Plaintiffs fail to plead the statements with the particularity required under Rule 9(b).

When considering a Motion to Dismiss an action based in fraud, the court must take into consideration Fed.R.Civ.P 9(b), which imposes a heightened pleading requirement on Plaintiffs. The Rule provides that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind may be averred generally." Id. The purpose of Rule 9(b) is to "give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits', and to prevent the filing of suits that simply hope to uncover relevant information during discovery." United States ex rel. Karvelas v. Melrose-Wakefield Hospital, 360 F.3d 220, 226 (1st Cir.2004), citing Doyle v. Hasbro, Inc., 103 F.3d at 194. The particularity requirement also enables defendants to prepare meaningful defenses. See Becher, 829 F.2d at 280.

a. Physician Statements

Before turning to an analysis of the statements, it is crucial to note that none of the accused statements discussed in this section were made by Defendants. Rather, Plaintiffs seek to hold Defendants liable for statements made by physicians who are neither parties to the instant matter, nor employees of the defendants. Whether Defendants may be held liable for fraudulent statements made by the physician speakers depends on the level of Defendants' involvement in, and control of, the seminars and speakers. See Bonilla, 150 F.3d at 72. Neither Plaintiffs nor Defendants have cited to authority to support or contradict the proposition that the physicians' statements can be imputed to Defendants. In the securities fraud context, the First Circuit has held that a defendant may be liable for a third-party's statements under certain circumstances. See In re Cabletron Systems, Inc., 311 F.3d 11, 37 (1st Cir.2002) (adopting for the first time the "entanglement test" developed by the Second Circuit). In Cabletron, the Court noted that liability may attach for third party statements where "the defendants have expressly or impliedly adopted the statements, placed their imprimatur on the statements, or have otherwise entangled themselves with the [third party] to a significant degree . . . [T]he court will determine whether the complaint contains allegations which, favorably construed and viewed in the context of the entire pleading, could establish a significant and specific, not merely a casual or speculative, entanglement between the defendants and the [third parties] with respect to the statements at issue." Id. at 37-38, citing Schaffer v. Timberland Co., 924 F. Supp.1298, 1310 (D.N.H.1996) (emphasis added). An entanglement claim "will be rejected if it merely suggests or assumes that company insiders provided the information on which [third parties based their statements]." In re Cabletron, 311 F.3d at 38, citing Suna v. Bailey, 107 F.3d 64, 73-74 (1st Cir.1997). This framework established by the First Circuit, albeit in a different context, identifies relevant factors

that should be considered when evaluating Defendants' liability for third party statements. Given the lack of briefing on this important question, it would be inappropriate for this Court to make a determination at this time of what standard or test should be applied. Whatever the precise contours of the substantive standards, the heightened pleading requirements that Rule 9(b) imposes upon Plaintiffs apply to allegations that a defendant is liable for a third party's statements. See In re Number Nine Visual Tech Corp. Sec. Litig., 51 F. Supp.2d 1, 31 (D. Mass.1999)(Young, C.J.).

Plaintiffs have set forth a series of allegations to support the allegation that Defendants "controlled the content" of the statements. They allege that Defendants achieved this control by funneling money to the medical marketing firms, who then paid the doctors, and that they "handpicked the speakers." Plaintiffs also allege that Defendants arranged and paid for the presentations at which the physicians made their statements. They buttress these allegations with specific allegations of payments made to identified doctors. The lack of any allegations that Defendants told the doctors what to say in advance arguably weighs against a finding of entanglement or imputed responsibility for the physician statements. "Entanglement also includes situations when company officials 'intentionally foster a mistaken belief.'" In re Cabletron, 311 F.3d at 38 (citation omitted). In light of the allegation that Defendants suppressed the results of negative studies, the allegations appear sufficient at this stage to allow Plaintiffs to proceed on the theory that Defendants are responsible for the doctors' statements.

The allegations involving statements made about pain, dose dependency, diabetic neuropathy, and monotherapy satisfy Rule 9(b)'s pleading requirements. Plaintiffs have alleged the "when" "where" and "who" of the statements with sufficient particularity, as they identify the

date, location, and speaker with specificity. Thus, although the exact content of each and every statement is not alleged with specificity, Plaintiffs have alleged enough about the substance of the statement to put Defendants on notice of the claim and allay Rule 9(b)'s concern regarding strike suits. Defendants have transcripts of all of the seminars; armed with the information provided by Plaintiffs in these allegations, they can easily locate the accused statements.

In addition, regarding pain, Plaintiffs have alleged "upon information and belief" that "similar statements" were made at several events. The First Circuit has consistently held that allegations based on information and belief do not satisfy Rule 9(b)'s particularity requirement unless the Complaint sets forth the facts on which the belief is founded. See Karvelas, 360 F.3d at 226 n.8; see also Becher, 829 F. 2d at 288, citing Wayne Investment, Inc. v. Gulf Oil Corp., 739 F.2d 11, 13 (1st Cir.1984). This strict rule applies "even when the fraud relates to matters peculiarly within the knowledge of the opposing party." Becher, 829 F.2d at 288 citing Wayne Investment, 739 F.3d at 14. At this stage, Plaintiffs have set forth sufficient facts to support their belief. They allege that the representative transcripts in their possession reveal that the same or similar statements were made at each presentation; once the content for a program was assembled, Defendants presented the program at various cities around the country; and as to at least one specific program, that Defendants "presented [it] dozens of times in 1998." ACC, ¶ 220. Further, the Complaints generally allege an organized marketing campaign repeating presentations in different locations. The foregoing allegations plead with particularity the basis for the "information and belief" and support the inference that statements materially similar to the identified ones were made at the other identified presentations.

The allegations involving statements made about restless leg syndrome, bipolar, and

panic disorder also survive Defendants' Rule 9(b) objection. As with the pain allegations, Plaintiffs detail the meetings at which the allegedly fraudulent statements were made. Although they do not identify the name of any speaker, given all of the surrounding detail, Defendants have more than ample notice in order to review the transcripts to prepare a defense. The First Circuit has held, albeit in a securities fraud context, that the absence of certain factors is not necessarily fatal to a complaint. Rather, it is the entire set of facts portrayed by a complaint that should be considered. See In re Cabletron, 311 F.3d at 32 ("Because a categorical approach is not appropriate, courts will allow private securities fraud complaints to advance past the pleadings stage when some questions remain unanswered, provided the complaint as a whole is sufficiently particular to pass muster under the [Private Securities Litigation Reform Act]").

However, Plaintiffs' allegations regarding social phobia fail to pass Rule 9(b) muster. All of these statements are alleged on information and belief, without any explanation of the basis of the belief that the statements were made. This is not enough under Rule 9(b). Plaintiffs also allege "upon information and belief" that negative studies indicated or found that Neurontin was not effective for social phobia. However, they do not provide the Court with supporting allegations, nor do they explain why they cannot plead the negative studies with particularity. Accordingly, this allegation fails under Rule 9(b).[19]

Finally, Plaintiffs also allege that statements were made regarding "other" unspecified

[19] This finding is not inconsistent with my previous finding that Plaintiffs had alleged sufficient facts to support their claims based on information and belief with regard to the statements about pain. There, Plaintiffs had alleged the particulars of several statements on pain, and also alleged that similar statements were made at all events. Here, Plaintiffs have failed to plead the facts which lead them to believe that such studies exist.

conditions. They do not identify any statement, any speaker or the date and location of any statement. Rule 9(b) does not permit such general pleading. See Feinstein v. Resolution Trust Corp., 942 F.2d 34, 42 (1st Cir.1991)(requiring plaintiffs to allege the time, place and content of alleged communications).

b. Statements by Pfizer's Representatives

For each and every statement in the Verbatim Reports that Plaintiffs attempt to attribute to medical liaisons, they fail to assert the identity of the speaker, and where and precisely when the statement was made. Rule 9(b) requires more than merely alleging that at sometime, or even during a given month, an unidentified medical liaison made a fraudulent statement about Neurontin or that, upon information and belief, the liaisons made fraudulent statements routinely. See Karvelas, 360 F.3d at 226; Becher, 829 F.2d at 288. If the Verbatim Reports sufficiently identified the "when" and "where" of the statement, Plaintiffs could overcome this problem. As the Complaints stand presently, that connection has not been made. Claims based upon the Verbatim Reports should therefore be dismissed for failure to meet Rule 9(b)'s pleading standards.

3. Failure to State a Claim

Defendants maintain that this matter should be dismissed for Plaintiffs' failure to state a claim under Rule 12(b)(6).[20] Plaintiffs advance the following different theories of fraud, each of

[20] Defendants also argue that Plaintiffs have failed to allege facts demonstrating that any of the statements at issue were actually false. As a general matter, however, the plaintiffs allege that Neurontin was ineffective for the conditions for which it was touted. Plaintiffs claim that

which requires a separate Rule 12(b)(6) analysis: (a) that Defendants stated or implied that placebo-controlled clinical studies had proven Neurontin to be effective when they had not; (b) that Defendants misrepresented the results of actual clinical studies; and (c) that Defendants committed fraud by promoting Neurontin either in the absence of supporting studies or in the face of negative or equivocal studies. ACC, ¶ 45.

a. Defendants Misrepresented That Scientific Studies Showed Neurontin Was Effective

For ease of discussion, I analyze this theory in light of the allegations Plaintiffs made with respect to Neurontin's efficacy for pain. Regarding pain, Dr. Longmire said that Neurontin was effective for the treatment of pain. According to Plaintiffs, this statement was false and/or misleading because Dr. Longmire did not have any evidence to support such claims, yet he implied that clinical trial evidence sufficient to establish causation existed. The words of the statement, even read in the context in which the statement was made and/or the allegations of the Complaints generally, do not represent that scientific evidence supports the effectiveness assertion. Neither the words nor the context of Dr. Longmire's statement suggests the existence of clinical research.

In fact, the allegations in the Complaints suggest that the physicians spoke primarily in anecdotal terms, making presentations based on their own individual experiences with

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defendants perpetrated a "fraudulent scheme to market and sell the drug Neurontin for a variety of uses for which it is not approved or medically efficacious." ACC, ¶ 1 (emphasis added), and restate the allegation again when they aver defendants marketed Neurontin for uses for which it was "neither approved or effective." ACC , ¶ 3. These allegations alone are enough to overcome defendants' objection that the Complaints fail to allege that the effectiveness statements were objectively false.

prescribing Neurontin. They may have also remarked on the experiences of their colleagues or other practicing physicians. For example, the Complaints allege that the doctors presented anecdotal evidence at every presentation concerning Neurontin's off-label use. ACC, ¶ 205. See also ACC ,¶ 40 (alleging payments to physicians to describe their off-label use); ¶ 133 (alleging that "At every presentation concerning Neurontin's use for pain, anecdotal evidence was presented to support Neurontin's use"); ¶ 147 (alleging "anecdotal evidence" was presented at "every" presentation regarding restless leg syndrome); ¶ 208 (alleging that medical liasions promoted Neurontin by providing "non scientific anecdotal information."). Furthermore, the Complaints make no allegations that any of the doctors knew these statements to be false at the time they spoke, or that these doctors intended to deceive the audience.

Plaintiffs also argue that the terms "effective" and "efficacy" have specific and well-understood meanings within the medical community. ACC, ¶ 125. The FDA will only find a drug to be "effective" if the proposed use is supported by well designed, placebo-controlled trials that establish a causal relationship to a statistically significant degree. Plaintiffs extrapolate that any statement that Neurontin is "effective" or "works"[21] is therefore understood to mean that well controlled clinical studies have been conducted and support the use of Neurontin for the indication at issue. ACC, ¶ 125. Plaintiffs provide no support for this conclusory allegation.

I find Plaintiffs' allegation that, for every instance identified in the Complaints, the term "effective" or "works" is understood the incorporate the above FDA standard, wholly conclusory

[21] Plaintiffs also assert that any statement that Neurontin "has been proven to" have a particular outcome is understood to mean that well controlled clinical studies have been conducted. Plaintiffs do not allege that any statement that Neurontin "has been proven to" have a particular outcome was made. Therefore, I do not consider this argument.

and lacking in specifics. See Lopez v. Bulova Watch Co. 582 F.Supp 755, 766 (D.R.I.1984) ("Here, the fraud count is almost wholly conclusory, and is sorely lacking in specifics. It is too vague to meet the Rule 9(b) benchmark"). The Court must draw all reasonable inferences in Plaintiffs' favor at this stage in the proceedings, even under the "minimal requirements" of Rule 12(b)(6). See Gooley v. Mobil Oil Corp., 851 F.2d 513, 514 (1st Cir.1988). Indeed, Rule 12(b)(6) is less stringent than Rule 9(b). See Cooperman v. Individual, Inc., 171 F.3d 43, 49 n. 8 (1st Cir.1999). Nonetheless, for an allegation to be a "fact" rather than a "conclusion," the "suggested inference [must] rise[] to what experience indicates is an acceptable level of probability." Id., quoting Dartmouth Review v. Dartmouth College, 889 F.2d 13, 16 (1st Cir.1989). Plaintiffs' allegations fail to meet this minimal standard. Accordingly, the mere use of the word "effective" in a statement by a doctor or other person in the medical field does not automatically represent that scientific research has been done to support Neurontin's use for a particular indication. This is especially so where, as here, the allegations in the Complaints indicate that the focus of the presentations was on the sharing of anecdotal information.

At another meeting, Dr. Schacter stated that "pain specialists are finding low dosages of Neurontin effective." This statement simply does not imply clinical trial support. Rather, Dr. Schacter merely stated that practicing doctors specializing in the treatment of pain are finding that (some) patients respond to Neurontin. Such an statement reporting anecdotal impressions or results does not in any way imply that clinical trials have proven it to be effective. Dr. Schacter did not represent that clinical studies had proven his statement to be true, nor is there any reasonable inference that he implied such a notion. Moreover, it is crucial to note that the Complaints do not allege that pain specialists were *not* finding Neurontin to be effective for the

treatment of pain, nor that Dr. Schacter did not believe his statements to be true.

Plaintiffs assert that any statement about Neurontin's use for off-label indications "that purports to rely on clinical or published evidence must also describe those clinical studies that have found that Neurontin is not effective for off-label uses." ACC, ¶ 126. They also assert that "anecdotal evidence of a drug's usefulness for a given condition could not be presented as the equivalent of the findings of a well-designed clinical trial." ACC, ¶ 127. Plaintiffs fail to allege any facts that support their argument that these statements purport to rely on clinical evidence, or that any anecdotal evidence offered by the speakers was presented as the equivalent of the findings of a scientific trial. Accordingly, Plaintiffs' allegations of a fraud based upon misrepresentations that scientific evidence supported Neurontin's use fail under 12(b)(6).

b. Defendants Misrepresented the Results of Scientific Studies.

Plaintiffs allege that in August of 1996 at a meeting in Jupiter Beach, Florida, Doctors Harden and LeRoy misrepresented the results of Pfizer's Clinical Study 945-82. According to Plaintiffs, the doctors not only falsely claimed that the study did not evidence a failure of Neurontin's efficacy for use as a monotherapy, but they also misrepresented the lack of a dose response. ACC, ¶ 167. In addition, Dr. LeRoy allegedly misrepresented that an Eastern European clinical trial was successful, when in fact the double blind codes of the study had not been broken and patient recruitment had not been completed. Id. Plaintiffs contend that the doctors could have received information about the status of these unpublished clinical trials only from Parke-Davis. Id.

Finally, Plaintiffs claim that in 1996, Parke-Davis funded a placebo-controlled clinical

trial conducted by Dr. Kenneth Gorson. On August 23, 1997, Dr. Gorson submitted a draft of his study to Parke-Davis, and his abstract stated that the study did not support Neurontin's use for diabetic peripheral neuropathy. It stated that Neurontin "is probably no more effective than placebo treatment in the treatment of painful diabetic neuropathy." In January 1998, Parke-Davis circulated a different abstract that concluded "Gabapentin may be effective in the treatment of painful diabetic neuropathy. Our results suggest that further studies evaluating higher dosages of gabapentin are warranted."

Dr. Gorson refused to adopt this revision. In February 1999, the results of his study were published in a letter to the editor of the Journal of Neurology, Neurosurgery & Psychiatry. The "article" concluded, "The results of this study suggest that gabapentin is probably ineffective or only minimally effective for the treatment of painful diabetic neuropathy at a dosage of 900 mg/day." Nonetheless, Parke Davis submitted to Drugdex a draft of the article which contained language consistent with the false abstract circulated by Parke-Davis but was not contained in the actual article. Drugdex's summary citation for the Gorson article stated "the authors suggest that higher doses of gabapentin are needed," and omitted the author's conclusion that gabapentin is "probably ineffective" for the treatment of painful diabetic neuropathy.

The foregoing allegations are set forth with sufficient particularity to comply with the requirements of Rule 9(b), and sufficiently state a claim for fraud pursuant to Rule 12(b)(6). As to the theory that Defendants misrepresented the results of clinical studies, therefore, the motions to dismiss should be denied.

c. Defendants Fraudulently Omitted Contrary Scientific Evidence or Failed to Disclose the Absence of Supporting Scientific Evidence.

Plaintiffs argue that their claims do not depend on proof that Neurontin was ineffective. Rather, they say that the absence of supporting scientific evidence that Neurontin is effective for unapproved uses renders Defendants' claims misleading and actionable. In this regard, Plaintiffs have alleged that all statements made regarding Neurontin's efficacy were either false or misleading because either (1) clinical evidence in existence did not support such claims; or (2) no studies had been done to support such claims. If Plaintiffs had plead statements representing scientific support for Neurontin's effectiveness, allegations of an absence of such evidence would render those statements fraudulent or misleading for purposes of a motion to dismiss. As already noted, however, Plaintiffs failed to plead any such statements. It is therefore a closer question as to whether Defendants: (1) had a duty, independent of the FDA regulations, to make fuller disclosures; (2) whether such a duty encompassed the doctors, and (3) whether any of the statements that Plaintiffs do plead can constitute actionable fraud absent affirmative evidence from Plaintiffs that Neurontin is ineffective.

Plaintiffs argue that half-truths, omissions, and non-disclosures are equally actionable. Indeed,

> "[T]he locus classicus of fraud is a seller's affirmative false statement or a half truth, i.e., a statement that is literally true but is made misleading by a significant omission. At common law, fraud doctrine did not impose any broader, general duty to disclose, but it is settled that the mail and wire fraud statutes go somewhat beyond the common law. Thus, a leading commentary on federal jury instructions says that even where there is no falsehood or half truth:
>
> [T]he failure to disclose information may also constitute a fraudulent representation. . .if the defendant was under a legal, professional, or contractual duty to make such a disclosure."

Bonilla, 150 F.3d at 69-70 (internal citations omitted). See also Kannavos v. Annino, 356 Mass.

42, 48 (1969)(holding that if one "speak[s] with reference to a given point of information . . . he is bound to speak honestly and to divulge all the material facts bearing upon the point that lie within his knowledge. Fragmentary information may be as misleading . . . as active misrepresentation, and half-truths may be as actionable as whole lies"(internal citations omitted)).

i. Fraudulent Omission of Contrary Scientific Evidence

Plaintiffs allege, in relation to a number of medical conditions, that Defendants knew of scientific studies that showed negative results regarding Neurontin's efficacy. For example, Parke-Davis' own clinical trial showed, by the third quarter of 1997, that a placebo was more effective for Bipolar Disorder than Neurontin; the same was true with respect to Panic Disorder and Diabetic Neuropathy. ACC, ¶¶ 138, 152, 164. The Complaints further allege that Defendants "suppressed" the negative results of these studies for several years. Defendants allegedly had similar results of a study of Neurontin's utility for migraine and, regarding migraine, they allegedly knew of several other reports of negative study results. ACC, ¶¶ 174-175.

For these conditions, Plaintiffs have stated a claim of fraud that survives Defendants' challenges under 12(b)(6). Whether or not Defendants had an affirmative duty to disclose, they made fraudulent or misleading statements in that Defendants hired the doctors to relate their positive anecdotal experiences despite knowing that scientific studies (the results of some of which Defendants had withheld) significantly contradicted and undermined the doctors' statements. No doubt the fuller factual record that will be before the Court at a later stage of the case may confirm or disprove Plaintiffs' allegations. The question presently before the Court,

however, is not whether Plaintiffs' will prevail on their Complaints, but whether Plaintiffs have alleged sufficient facts to state a claim.

ii. Failure to Disclose the Absence of Supporting Scientific Evidence

Plaintiffs allege that physician speakers stated that Neurontin was effective for pain and a variety of other conditions, without revealing that no studies had been conducted. According to Plaintiffs, the mere absence of clinical studies renders such statements misleading. Other than the FDA regulations (which Plaintiffs may not enforce, *supra*) or voluntary codes of compliance, however, Plaintiffs point to no affirmative obligations upon Defendants to make disclosures. Moreover, hiring a doctor to relate the positive experiences that patients have had with Neurontin with a disorder such as pain, does not constitute a false or fraudulent representation. This is true even when Defendants know when they hire the doctor to speak that no scientific study either supports his experiences or contradicts his apparent results. The Complaints are devoid of any allegations that the doctors misrepresented the anecdotal experiences they described. Notably, this is not a case where Defendants are alleged to have fed false information to the physician speakers, whether such information be scientific or anecdotal. See, e.g., Franklin,147 F.Supp.2d at 48-49. Although Plaintiffs allege that Neurontin was not effective for the conditions at issue, they do not allege that doctors were not finding it to be effective. Therefore, as pled, Plaintiffs cannot maintain their claims on a theory that Defendants failed to disclose that no scientific studies had been done. See Bonilla, 150 F.3d at 70 ("It would be a truly revolutionary change to make a criminal [or defrauder] out of every salesman . . . who did not take the initiative to reveal negative information about the product and who –a jury might find– harbored in his heart the hope that the buyer would never ask").

Plaintiffs' allegations regarding the promotion of Neurontin for social phobia fail,[22] though for somewhat different reasons. On July 22, 1997 Parke-Davis received results from a clinical study that showed Neurontin to be "generally favorable" on a small sample that completed the study. Plaintiffs make no allegations that Parke-Davis knew of negative studies regarding social phobia; rather, they assert that the results of this study were "problematic." Specifically, they contend that the study revealed "inexplicable discrepancies" in efficacy between male and female subjects and between people 35 years of age and older as compared to those younger. ACC, ¶¶ 158-159. Without more, these general allegations of the alleged limits of the results of one scientific study fail to render fraudulent, false or misleading the anecdotal statements by individual doctors that Neurontin is effective.

Finally, with regard to restless leg syndrome, Plaintiffs fail to allege the existence of a negative study. According to Plaintiffs, in 1996 Dr. Bruce Ehrenberg examined whether Neurontin was effective for "periodic limb movement, a sleep disorder closely related to [but not the same as] restless leg syndrome." ACC, ¶ 144. Less than half of the participants in the periodic limb movement study had improved sleep, Neurontin had no effect on more than half, and the drug did not affect any participants' limb movements during sleep. Id. These allegations fail to plead with particularity the connection between periodic limb movement and restless leg syndrome. Without this connection, it is not plausible that Plaintiffs can prove a set of facts that renders false and misleading statements about Neurontin's effectiveness for one syndrome based upon the negative results of a study pertaining to another syndrome.

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[22] Although the allegations regarding Social Phobia failed to survive the Defendants' Rule 9(b) objection, I analyze them here as well for the sake of completeness.

d. Miscellaneous

Plaintiffs claim that one article widely circulated by Defendants concerning restless leg syndrome asserted that the authors, Gary and Larry Mellick, had not and would not receive financial benefit from anyone with an interest in Neurontin. The brothers had actually received tens of thousands of dollars for acting as speakers at Defendants' events, and Gary Mellick never disclosed that he was a consultant with Parke-Davis and was assisting the company in developing the market for off-label use of Neurontin. ACC, ¶ 116. This omission fails as a cause of action for two reasons: Plaintiffs make no allegations and cite no legal authority to support a conclusion that Dr. Mellick had any duty to disclose his consultancy; and nothing in the record to suggest that his failure to do so can be imputed to Defendants.

In addition, Plaintiffs allege that one MES article published in CNS Spectrums noted that "an honorarium was received from Medical Educational Systems for preparation of this article." However, the article did not reveal that Parke-Davis had paid and retained MES. For the reason set forth above in connection with the article by Dr. Mellick, claims based upon this omission should be dismissed.

4. Violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

This statute prohibits "any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission, of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale or advertisement of any merchandise." N.J.S.A. 56:8-2.

Plaintiffs have alleged that Defendants committed fraud in connection with the promotion

of Neurontin. At this stage, their claims under New Jersey law can proceed. Defendants challenge the Count under this statute on the ground that the NJCFA does not protect plaintiffs who are not residents of New Jersey, and thus should be dismissed. However, this issue is more appropriately left for resolution at either the class certification or summary judgment stage, when the laws of the fifty states will be applied to discrete groups of plaintiffs based upon their domicile, especially where it appears that the proposed class would include residents of New Jersey in any event.[23]

5. Common Law Fraud (Count IV)

In Massachusetts, to succeed on a common law fraud claim, a plaintiff must show that defendant falsely represented a material fact, for the purpose of inducing the victim to act thereon, and that the victim did rely on the representation to his detriment. See Barrett Assocs. v. Aronson, 346 Mass. 150, 152 (1963).

As discussed above, Plaintiffs alleged that Defendants are responsible for fraudulent statements made with the intent to induce prescriptions of Neurontin for off-label purposes. As discussed above in connection with the statement by statement analysis, Plaintiffs have alleged enough for their claim of fraud to survive a Motion to Dismiss.

6. Unjust Enrichment

To sustain a claim for unjust enrichment, Plaintiffs must show "(1) an enrichment, (2) an

[23] Defendants also challenge this count with the argument that because the TPPs are large sophisticated business entities, they are not within the class of "persons" that are to be protected under the NJCFA. However, whether the TPPs have standing to bring a claim under the NJCFA is more appropriately resolved at the class certification or summary judgment stage.

impoverishment, (3) a relation between the enrichment and the impoverishment, (4) the absence of justification and (5) the absence of a remedy provided by law." In re Lupron, 295 F.Supp.2d at 182 (citations omitted).

Defendants argue that without an allegation that Neurontin is ineffective, there can be no loss and therefore no claim of unjust enrichment. As already noted, however, Plaintiffs have made such an allegation. Next, Defendants argue that Plaintiffs have failed to establish causation. Again, as already noted, Plaintiffs have satisfied this requirement. Finally, Defendants argue that the claim is barred under a three year statute of limitations. That issue is considered below.

I do note that Plaintiffs state that they have alleged that Defendants were enriched by billions of dollars at Plaintiffs' expense, by engaging in a deceptive campaign of off-label promotion in violation of federal laws. Unjust enrichment is an equitable claim, and is not available to Plaintiffs who have an adequate remedy at law. See Davis v. Cox, 356 F.3d 76, 95 (1st Cir.2004). Because I recommend that the Class Plaintiffs' state law fraud claims survive in some respects, Class Plaintiffs have an adequate remedy at law. Accordingly, I recommend that the Court ALLOW the Motion to Dismiss the Class Plaintiffs' Unjust Enrichment claim. In addition, I recommend that the Court DENY the Motion to Dismiss the Coordinated Plaintiffs' Unjust Enrichment claim because they have no adequate remedy at law due to their failure to allege cognizable injury.

7. First Amendment

Defendants argue that the doctors' statements concerning uses of Neurontin for off-label

uses are protected under the First Amendment as scientific speech. This argument has no application to this case because "[T]he First Amendment does not shield fraud . . . 'the intentional lie' is 'no essential exposition of ideas.'" Illinois, ex rel. Madigan v. Telemarketing Associates, Inc., 538 U.S. 600, 612 (2003)(internal citation omitted). The Complaints advance claims of fraud arising out of allegedly fraudulent, false and misleading statements. Because, as already noted, mere truthful off-label promotion is not fraud, this case does not present the difficult First Amendment issues Defendants advance.[24]

8. Statute of Limitations

Civil RICO claims are subject to a four-year statute of limitations. Agency Holding Corp v. Malley-Duff & Assoc., Inc., 483 U.S. 143, 156 (1987). The statute begins to run when a plaintiff knew or should have known of the injury. See Rotella v. Wood, 528 U.S. 549, 553 (2000).

Defendants argue that the alleged injury is payment for the off-label uses, so the statute began to run when Plaintiffs paid for their prescriptions, in many cases over ten years ago.[25] At the very

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[24] In fact, Defendants note that the FDA itself is struggling with how to ensure that its own guidelines and regulations comply with the First Amendment. To that end, the FDA has sought public comment, with particular attention to whether the First Amendment restricts the "FDA's ability to regulate speech concerning off-label uses." (Defendants' Memorandum at 28, citing the U.S. Dept. of Health and Human Services, Food and Drug Administration, Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942-44 (2002)).

[25] Defendants' second argument is that Plaintiffs have failed to plead fraudulent concealment with the requisite particularity. Plaintiffs have alleged that Defendants' conduct was hidden because they hid their financial connections between the participating physicians and used the medical marketing firms as intermediaries.

To maintain a claim of fraud or concealment, Plaintiffs must demonstrate that "(1) defendants engaged in a course of conduct designed to conceal evidence of their alleged wrong-doing and that (2) [the plaintiffs] were not on actual or constructive notice of that evidence, despite (3) their exercise of reasonable diligence." J. Geils Band Employee Benefit Plan v. Smith Barney Shearson, Inc., 76 F.3d 1245, 1255 (1st Cir.1996).

least, they argue, plaintiffs were aware of their injury in January of 2000, when the *Qui Tam* Complaint was unsealed, or in March of 2000 when Warner-Lambert disclosed in an SEC filing that it was being investigated by the US Attorney's Office. In addition, the probe was mentioned in articles in the *Wall Street Journal* and the *Pink Sheet*, a trade publication, on March 30, 2000 and on April 3, 2000, respectively. Yet the Coordinated Complaint was not filed until May 14, 2004, and the Class Complaint was not filed until June 2, 2004, both more than four years later.

Plaintiffs note that the statute of limitations runs when plaintiffs are on notice that they may have been defrauded. See Blue Cross of California v. SmithKline Beecham Clinical Labs, Inc., 108 F.Supp.2d 116, 122 (D.Conn.2000). They note, correctly, that the statute of limitations is generally a jury issue. The First Circuit has been very reluctant to leave the determination of when a plaintiff should have been on notice of his injury to the court. Rather, it is an issue best determined by the fact finder. See Young v. Lepone, 305 F.3d 1, 12 (1st Cir.2002). Therefore, I recommend that the Court reject this argument as a basis for dismissal.

IV. CONCLUSION

For the foregoing reasons, I make the following recommendations on Defendants' Motions to Dismiss (Docket #s 58 and 59).

1) As to the Amended Class Complaint, I recommend that the Court ALLOW Defendants' Motion in part and DISMISS Counts I (RICO); II (RICO Conspiracy); and V (Unjust Enrichment). I recommend that the Court DENY the Motion with respect to Counts III (New Jersey Consumer Fraud Act) and IV (common law fraud). However, Plaintiffs should be permitted to proceed with

Counts III and IV only insofar as the counts are based on the theories (1) that Defendants misrepresented the results of scientific studies; and/or (2) that Defendants fraudulently failed to disclose existing negative clinical evidence.

2) As to the Coordinated Complaint, I recommend that the Court ALLOW Defendants' Motion and DISMISS Counts I through IX (RICO Counts). Because the Coordinated Complaint fails to allege a cognizable injury suffered by the Coordinated Plaintiffs, I also recommend that the Court DISMISS Counts X-XII.[26] Finally, I recommend that the Court DENY the Motion with respect to Count XIII (Unjust Enrichment).

[26] Defendants do not address specifically Counts X through XII of the Coordinated Complaint, which allege violations of California's Unfair Competition Law (Count X); violations of the consumer protection statutes of the remaining 49 states (Count XI); and insurance fraud in violation of Pennsylvania law (Count XII). Defendants do, however, seek dismissal of the Complaints entirely.

3) Finally, I recommend that the Court allow Plaintiffs to file amended complaints within sixty (60) days from the date of the Court's ruling on this Report and Recommendation.[27]

/s/ LEO T. SOROKIN
Leo T. Sorokin
UNITED STATES MAGISTRATE JUDGE

[27] The parties are hereby advised that under the provisions of Fed. R. Civ. P. 72, any party who objects to these proposed findings and recommendations must file specific written objections thereto with the Clerk of this Court within 10 days of the party's receipt of this Report and Recommendation. The written objections must specifically identify the portion of the proposed findings, recommendations, or report to which objection is made and the basis for such objections. The parties are further advised that the United States Court of Appeals for this Circuit has repeatedly indicated that failure to comply with Rule 72(b) will preclude further appellate review of the District Court's order based on this Report and Recommendation. See Keating v. Secretary of Health and Human Services, 848 F.2d 271 (1st Cir.1988); United States v. Emiliano Valencia-Copete, 792 F.2d 4 (1st Cir.1986); Park Motor Mart, Inc. v. Ford Motor Co., 616 F.2d 603 (1st Cir.1980); United States v. Vega, 678 F.2d 376, 378-379 (1st Cir.1982); Scott v. Schweiker, 702 F.2d 13, 14 (1st Cir.1983); see also, Thomas v. Arn, 474 U.S. 140, 106 S.Ct. 466 (1985).